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Via ECF
Hon. Katherine Polk Failla
Thurgood Marshall
United States Courthouse
40 Foley Square
New York, NY 10007

Re: *In re: Chantix (Varenicline) Mktg., Sales Practices and Prods. Liab. Litigation (No. II)*, 22-MD-3050 (KPF), 22-mc-3050 (KPF) (S.D.N.Y.)

Dear Judge Failla:

Pursuant to Section VI.C of the Court's January 6, 2023 Order (ECF No. 6), Defendant Pfizer, Inc. ("Pfizer") and Temporary Plaintiffs' Counsel jointly submit the following proposed agenda for the initial conference and discuss each side's views of the forthcoming motions and the case trajectory, including proposing a schedule for the litigation.[1]

Proposed Agenda. The parties propose the following agenda items for the April 7 conference:

1. Appointment of Interim Lead Plaintiffs' Counsel, Liaison Counsel, and potential Plaintiffs' Executive Committee
2. Theories of Harm and Differences Among Plaintiffs
3. Impact of Dismissal of *Harris*
4. Plaintiffs' Request for Leave to File Consolidated Complaint
5. Substantive Motions and Case Trajectory
6. Proposed Schedule

The parties set forth their respective views on the foregoing agenda items below.

1. Appointment of Interim Lead Plaintiffs' Counsel, Liaison Counsel, and Potential Plaintiffs' Executive Committee

Temporary Plaintiffs' Counsel set forth all current Plaintiffs' views on appointment in their public and *in camera* submissions of March 17, 2023. Plaintiffs will be prepared to discuss same at the April 7 hearing. In light of the Court's memo endorsement of March 27, 2023 (D.E. 24),

[1] Various portions of this letter reflect the parties' respective positions on certain issues raised by the Court. The inclusion of those positions in this letter does not mean the other side agrees with the opposing side's characterizations.

Temporary Plaintiffs' Counsel are prepared to modify their appointment proposal to include only three interim co-lead counsel (Ruben Honik, Jorge Mestre, Charlie Schaffer) and one local New York attorney as liaison counsel (Joseph P. Guglielmo), with no Plaintiffs' Executive Committee. They are prepared to submit a proposed order for the Court's consideration either before or after the April 7 conference. Pfizer does not take any position on Plaintiffs' appointment requests.

2. Theories of Harm and Differences Among Plaintiffs

Plaintiffs' Position

Plaintiffs assert that this MDL consists of actions brought by consumer Plaintiffs, third-party payors ("TPPs"), and Plaintiffs seeking medical monitoring. As alleged, all actions brought by those three groups are based on Pfizer's manufacture and sale of Chantix drugs that were contaminated with N-nitroso-varenicline, a genotoxic carcinogen, and which were not made in compliance with current Good Manufacturing Practices ("cGMPs"). As a result of each of the foregoing, the various Plaintiffs allege Pfizer's Chantix drugs were adulterated, misbranded, and economically worthless.

All actions involve the same causes of action. There are minor differences as to the person or entity that paid for the adulterated Chantix and the specific remedies sought. Both the consumer Plaintiffs and the TPPs are seeking damages for the amount they paid to purchase adulterated Chantix. The consumer Plaintiffs are seeking damages for the amounts that they paid in the form of co-pays, co-insurance, deductibles, or uninsured cash purchases, as well as replacement/return costs for unused recalled Chantix. TPPs, such as insurers, seek damages for the amounts they paid/reimbursed for those Chantix purchases on behalf of their insureds.

As for the medical monitoring Plaintiffs, they are individuals that purchased and ingested the contaminated Chantix. N-nitroso-varenicline, as alleged, is a known genotoxic cancer-causing nitrosamine, and the medical monitoring Plaintiffs are seeking damages for medical testing, monitoring, and treatment related to having ingested same.[2]

Plaintiffs do not believe that there are substantive differences between the groups of Plaintiffs that would affect the course of the litigation.

Pfizer's Position

Pfizer believes that each category of Plaintiffs is similar in that they all assert economic losses stemming from payments made for Chantix prescriptions, but none has alleged a cognizable injury. Chantix is a highly effective prescription medicine that patients take short-term to help them quit smoking, which causes one out of every three cancer deaths each year in the United

[2] Pending appointment of leadership, all current Plaintiffs' counsel have conferred and have agreed not to proceed with medical monitoring claims were the Court to allow the filing of a single Master Complaint (*see infra* § 4).

States. After testing of Chantix identified the presence of a newly-discovered nitrosamine called N-nitroso-varenicline, Pfizer voluntarily recalled Chantix despite the fact that "[t]here [was] no data available to directly evaluate the carcinogenic potential of N-nitroso-varenicline."[3] As the Food & Drug Administration ("FDA") informed patients, "there [wa]s no immediate risk to patients taking this medication," and "the health benefits of stopping smoking outweigh the cancer risk from the nitrosamine."[4] As a result, the Chantix recall was classified as Class II, which means that the FDA determined that "the probability of serious adverse health consequences is remote."[5]

Pfizer's decision to voluntarily recall Chantix was a precautionary measure, not based on evidence of any actual cancer risk associated with real-world use of the medication. And no Plaintiff has asserted physical injury claims here, nor has any Plaintiff asserted that Chantix did not work as intended to help the patient stop smoking. A medication is not worthless if it worked as intended. Moreover, Pfizer offered patients reimbursement for the cost of any unused Chantix. As a result, no Plaintiff can establish injury.

Certain consumer Plaintiffs also have asserted claims for medical monitoring due to the theoretical cancer risk posed by N-nitroso-varenicline. But they also cannot plausibly allege an injury because they do not have a significantly increased risk of cancer attributable to Chantix.[6]

3. Dismissal of *Harris*

Plaintiffs' Position

Plaintiffs do not believe dismissal of *Harris* is dispositive of current Plaintiffs' claims and any forthcoming Master Complaint. Judge Cote largely dismissed *Harris* on pleadings deficiencies. She found that the *Harris* Plaintiffs insufficiently pleaded basic elements of their state-law claims, such as knowledge (*see* 586 F. Supp. 3d at 241), any fraudulent statements or omissions (*id.* 240-242, 243-44), and duties on Pfizer's part (*id.* at 243). The *Harris* complaint also lacked many allegations that have proven important on other nitrosamine contamination cases,

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[3] Food & Drug Administration, *FDA alerts health care professionals and patients to a voluntary recall of varenicline (Chantix) to the warehouse level* (July 2, 2021), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix.

[4] *Id.*

[5] *See* FDA, *Industry Guidance For Recalls: Recalls Background and Definitions*, https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions (last visited Mar. 31, 2023).

[6] While Pfizer does not believe any Plaintiff will be able to state a plausible claim, in the event the Court does not dismiss Plaintiffs' claims at the pleading stage, Pfizer anticipates that there will be differences in categories of Plaintiffs or types of claims that are relevant at the class certification stage.

such as allegations about Pfizer's violations of current Good Manufacturing Practices ("cGMPs"), whether contaminated Chantix is therapeutically equivalent to properly-made Chantix, and numerous other issues.

Also, since *Harris*, numerous other courts have favorably viewed nitrosamine contamination cases just like this one. *See, e.g.*, *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, MDL No. 19-2875, 2023 WL 181922 (D.N.J. Feb. 8, 2023) (certifying consumer and TPP state-law claims for economic losses relating to purchases of valsartan contaminated with nitrosamines, grouping certified claims into 93 state-law subclass groupings); *In re Metformin Mktg. & Sales Prac. Litig.*, No. 20-cv-2324, D.E. 251 (D.N.J. Jan. 31, 2023) (largely denying motions to dismiss consumer and TPPs' state law claims for economic losses relating to purchases of metformin contaminated with nitrosamines). Similarly, numerous other courts have upheld similar allegations in cases concerning the contamination of consumer products. *See generally, e.g.*, *Clinger v. Edgewell Personal Care Brands, LLC*, 2023 WL 2477499 (D. Conn. Mar. 13, 2023) (largely denying motion to dismiss case concerning sunscreen products contaminated with benzene); *Barnes v. Unilever United States Inc.*, 2023 WL 2456385 (N.D. Ill. Mar. 11, 2023) (largely denying motion to dismiss case concerning antiperspirant product contaminated with benzene); *Barnes v. Unilever United States Inc.*, 2022 WL 2915629 (N.D. Ill. July 24, 2022) (same); *Gagetta v. Walmart, Inc.*, --- F. Supp. 3d ---, 2022 WL 17812924 (N.D. Cal. Dec. 19, 2022) (largely denying motion to dismiss case concerning spices product contaminated with heavy metals); *Gonzalez v. Pepsico, Inc.*, 489 F. Supp. 2d 1233 (D. Kan. 2007) (largely denying motion to dismiss case concerning soda product contaminated with benzene). *Sitt v. Nature Bounty*, 2016 WL 5372794 (E.D.N.Y. Sept. 26, 2016) (largely denying motion to dismiss concerning supplements contaminated with small amounts of lead). The brand versus generic drug distinction latched onto by the *Harris* court is a distinction without difference. *See, e.g.*, *In re Zantac (Ranitidine) Prods. Liab. Litig.*, MDL No. 2924, 2021 WL 4593961, at *8 (S.D. Fla. Oct. 6, 2021) (denying branded-drug manufacturers' motion to dismiss economic loss class action alleging nitrosamine contamination of branded drug and its generic equivalents). Further, the *Harris* court's reasoning that "contaminated Chantix is still Chantix" (*see* 586 F. Supp. 3d at 241) rests on dubious logic. No consumer or TPP bargained for an adulterated or misbranded product that contained nitrosamines or which was made without adequate quality assurances. Other courts have noted that similar claims alleging adulterated or misbranded drugs regarding various products are unsafe and illegal to sell under federal law, and therefore worthless. *See, e.g.*, 21 U.S.C. §§ 331(a), 352; *see also Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019); *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, MDL No. 19-2875, 2021 WL 222776, at *16 (D.N.J. Jan. 22, 2021). Plaintiffs anticipate discussing this and more in response to Pfizer's anticipated motion to dismiss any forthcoming Master Complaint.

Pfizer's Position

As the Court knows, the first-filed putative class action, which arose from the same recall and made nearly identical allegations, was filed in this District and assigned to Judge Denise Cote. Judge Cote dismissed the first-filed complaint with prejudice under both New Jersey and New

York law. *See Harris v. Pfizer Inc.*, 586 F. Supp. 3d 231 (S.D.N.Y. Feb. 16, 2022). Pfizer believes that *Harris* bears directly on the viability of Plaintiffs' claims and that this Court should dismiss the anticipated consolidated complaint on the same (and potentially additional) grounds. In all of the complaints filed to date, Plaintiffs allege that Pfizer should have disclosed to consumers the presence of a newly-discovered nitrosamine when they purchased Chantix. Judge Cote already dismissed with prejudice claims based on this same premise.

The Plaintiffs in *Harris* asserted that Pfizer made misleading statements when it informed consumers that the medicine was "Chantix" as approved by the FDA and/or "that the product contained only the active ingredient varenicline" and also omitted the presence of the novel nitrosamine in product labeling and advertising. 586 F. Supp. 3d at 240. In dismissing these claims, Judge Cote held that the Plaintiffs had not pled that Pfizer made a misleading statement because (1) the potential "presence of a contaminant does not render the brand name on the label false–contaminated Chantix is still Chantix" and (2) "neither the product label nor the medication guide state that varenicline is the *only* biologically active ingredient in Chantix." *Harris*, 586 F. Supp. 3d at 241. As to the alleged omission, Judge Cote explained that Pfizer did not have a duty to disclose. *Id.* at 244. In reaching this holding, Judge Cote rejected as distinguishable Plaintiffs' reliance on *In re Valsartan, Losaratan & Irbesartan Products Liability Litigation*, 2021 WL 222776 (D.N.J. Jan. 22, 2021).[7] The *Harris* Plaintiffs did not appeal that ruling.

Thus, contrary to the Plaintiffs' assertion, Judge Cote's ruling was not simply based on a pleading deficiency but a fundamental defect that cannot be remedied by amendment. Any consolidated complaint asserting claims stemming from Pfizer's alleged failure to disclose the presence of the novel nitrosamine in Chantix should similarly fail as a matter of law.

4. Plaintiffs' Request for Leave to File Consolidated Master Complaint

As indicated in Temporary Plaintiffs' Counsel letter of March 21, 2023, all current Plaintiffs are in agreement that a single consolidated master complaint, inclusive of all current Plaintiffs and their respective class claims, would be the most efficient means to proceed in this matter. Pfizer does not disagree, provided that (1) any consolidated complaint is filed after formal appointment of interim lead Plaintiffs' counsel, and (2) the consolidated complaint supersedes all existing complaints.

5. Substantive Motions and Case Trajectory

In the event the Court grants leave for Plaintiffs to file a consolidated master complaint, Pfizer intends to move to dismiss that complaint. The parties request that the Court agree to waive its pre-motion letter requirement under Section 4.A of its Individual Rules of Practice in Civil

[7] Plaintiffs' reliance on additional decisions neither addressing the novel nitrosamine at issue nor the Chantix label does not change this result, as will be outlined in Pfizer's forthcoming motion to dismiss.

Cases for the motion to dismiss, and the parties agree that Plaintiffs would file the consolidated master complaint within 14 days after the appointment of Plaintiffs' interim lead counsel. The parties have reached agreement on the remainder of the schedule for briefing of the motion to dismiss:

Event	Parties' Proposal
Filing of Motion to Dismiss	45 days from filing of any Consolidated Master Complaint
Filing of Response to Motion to Dismiss	45 days from filing of Motion to Dismiss
Filing of Reply in Support of Motion to Dismiss	21 days from filing of Response to Motion to Dismiss

Plaintiffs believe fact discovery should commence immediately following the April 7 conference, especially since a number of the underlying cases have been pending now for 1.5 years. *See, e.g.*, *Republic of Turkey v. Christie's Inc.*, 316 F. Supp. 3d 675, 677-78 (S.D.N.Y. 2018) (denying stay for failure to show good cause); *Hong Leong Finance Ltd. (Singapore) v. Pinnacle Performance Ltd.*, 297 F.R.D. 69, 72 (S.D.N.Y. 2013) ("A motion to dismiss does not automatically stay discovery[.]"); *In re Aluminum Warehousing Antitrust Litig.*, No. 1:13-md-02481, D.E. 154 at 1 (S.D.N.Y. Feb. 6, 2013).

Pfizer believes that consistent with the Court's usual practice, discovery should be stayed pending a resolution on Pfizer's forthcoming motion to dismiss. As this Court has held, "its practice is to stay discovery until it renders its decision on any pending motions to dismiss." *SEC v. Farnsworth*, Case No. 1:22-cv-8226-KPF, ECF No. 30 (Oct. 28, 2022) (Failla, J.); *see also Geller Biopharm, Inc., v. Amunix Pharm., Inc.*, Case No. 1:20-cv-04334 (KPF), ECF No. 27 (Sept. 9, 2020) (Failla, J.) ("[T]he Court sees no reason to expend the Court's and the parties' time and resources pursuing discovery should the case be fully disposed of upon resolution of Defendant's anticipated motion to dismiss"); *Binz v. Amadeus It Grp., S.A.*, Case No. 1:15-cv-05457-KPF, ECF No. 135 (Nov. 30, 2015) (Failla, J.) ("[M]y own experience as a practitioner and my own experience as a Judge has shown me nothing but bad things when I have discovery running concurrently with a motion to dismiss."); *A.V.E.L.A., Inc. v. The Estate Of Marilyn Monroe, LLC*, Case No. 1:12-cv-04828-KPF, ECF No. 278 (Oct. 14, 2016) (Failla, J.) (staying discovery pending resolution of motions to dismiss). If the Court would prefer, Pfizer is prepared to file a motion to stay discovery.

6. Proposed Schedule Beyond Pfizer's Forthcoming Motion to Dismiss

The parties anticipate that the following non-discovery motions may be filed in the action: (1) Plaintiffs' motion for class certification; (2) *Daubert* motion(s) to exclude expert testimony; (3) motions for summary judgment and (4) motions in limine to exclude evidence.

Plaintiffs propose the below pretrial schedule and believe the proposed schedule provides for the efficient prosecution of the MDL. Because of the substantial overlap between class and non-class discovery, Plaintiffs believe that full merits discovery should immediately proceed in the action. Plaintiffs propose broad discovery parameters, but the parties can meet and confer to discuss the entry of interim scheduling dates that will govern the timing of document collection, search, and productions, and the service of privilege logs. Plaintiffs also intend to immediately begin negotiating an ESI protocol and confidentiality order to govern the action.

Pfizer believes that only the schedule for briefing its motion to dismiss should be set at this time. If the Court, however, would prefer to set a schedule for further activities, Pfizer proposes dates keyed from the Court's decision on Pfizer's motion to dismiss, should any subsequent proceedings be necessary.

Event	Plaintiff's Proposal	Pfizer's Proposal
Opening of fact discovery	14 days after the Initial Conference (April 21, 2023)	To commence after ruling on Pfizer's Motion to Dismiss (if needed)
Parties to serve their Initial Disclosures under Federal Rule of Civil Procedure 26(a)	14 days after the Initial Conference (April 21, 2023)	14 days after ruling on Motion to Dismiss
Deadline for adding any new parties	30 days after Court rules on Pfizer's Rule 12 motion	30 days after ruling on Motion to Dismiss
Deadline for substantial completion of document production	180 days after the Initial Conference (October 4, 2023)	240 days after the opening of fact discovery
Deadline for substantial completion of depositions	270 days after the Initial Conference (January 2, 2024)	390 days after the opening of fact discovery
Close of fact discovery	450 days after the Initial Conference (July 1, 2024)	420 days after the opening of fact discovery
Plaintiffs' motion for class certification with any class certification expert report(s); Plaintiffs to provide two dates on which each expert is available, between 30-60 days after motion filed	300 days after the Initial Conference (February 1, 2024)	30 days after fact discovery closes
Pfizer's opposition to motion for class certification with any class certification expert report(s) (with any *Daubert* motions); Pfizer to provide two dates on which each expert is	345 days after the Initial Conference (March 18, 2024)	90 days after motion for class certification is filed

Event	Plaintiff's Proposal	Pfizer's Proposal
available, between 30-60 days after opposition filed		
Plaintiffs' reply in support of motion for class certification with any rebuttal expert reports (with any opposition to Pfizer's *Daubert* motions and motions in support of Plaintiffs' *Daubert* motions of Pfizer's experts); Plaintiffs to provide two dates on which each rebuttal expert is available, between 21-42 days after reply filed	390 days after the Initial Conference (May 1, 2024)	90 days after opposition to class certification is filed
Pfizer's response to any *Daubert* motions filed by Plaintiffs as to Pfizer's experts	435 days after the Initial Conference (June 17, 2024)	60 days after Plaintiffs file their Daubert motions
Any summary judgment motions to be filed	30 days following the Court's ruling on Plaintiffs' motion for class certification	60 days following the Court's ruling on Plaintiffs' motion for class certification
Pretrial conference	To be determined by Court	To be determined by Court

The parties look forward to addressing any questions this Court has about the contents of this letter and the parties' scheduling proposals at the upcoming conference.

Respectfully,

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cc: Counsel of Record (via ECF)